

CORRELATION OF CORNEAL AND SCLERAL TOPOGRAPHY IN CASES WITH ECTASIAS AND NORMAL CORNEAS: THE SSSG STUDY

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ABSTRACT

Background and Objective

To determine the relationships between corneal and scleral elevation topography in subjects with corneal ectasias and normal corneas.

Material and Methods

This is a multi-site retrospective study. Ocular surface topography (sMap3D, Precision Ocular Metrology, US) was collected on 115 eyes with prolate cornea profile (Group A) and 227 eyes showing corneal ectasia (Group B). Sagittal height (SAG 1) was measured in the axis of the highest elevated point of the cornea (apex), defined by the meridian joining this apex to the geometrical center of the cornea at an 16 mm chord diameter (8-mm radius). Another sag value was evaluated 180° away (SAG 2) at the same diameter/radius. The difference in height between SAG 1 and SAG 2 represents a quadrant specific effect (QSE). Conjunctival toricity is estimated by comparing the best fit of the conjunctival/scleral shape data to a toric (Sin^2) curve; the root-mean-squared error (RMSE) of this curve, a measure of irregularity, was also calculated.

Results

The ectasia subjects demonstrated greater QSE, ($p < 0.001$), standard toricity ($p < 0.001$) and RMSE ($p < 0.001$) on the sclera compared to normal cornea cases. If the apex of the ectasia was ≥ 1.25 mm from the corneal center, the asymmetry was greater. Within the Group A, standard toricity was significantly higher than QSE ($p < 0.001$) suggesting a more regular conjunctival pattern. As a proof, a significantly greater proportion of cases in Group B vs. Group A (57% vs. 26%, $p < 0.001$) were found with conjunctival irregular shape, as previously defined. In both groups, subjects graded as having spherical/toric scleral shape had significantly lower RMSE values than those graded as having irregular shapes ($p < 0.001$).

Conclusion

Subjects with corneal ectasia have a different scleral shape compared to those with normal corneal profiles, largely presenting as a quadrant specific effect along the same axis. This difference is higher if the apex of the ectasia is ≥ 1.25 mm from the corneal center. RMSE seems to correlate with scleral shape classification in both groups.

Scleral lens fitting continues to develop as the standard of care for refractive treatment of patients with irregular corneal astigmatism or presenting ocular surface disorders. Specifically, these lenses are most commonly fitted on patients with keratoconus, and are increasing in use for patients with normal corneal shape such as those with dry eye diseases. Accordingly, the shape of the sclera and the overlying conjunctiva where the scleral lens lands, has become a great interest to the scleral lens practitioner community. The Scleral Shape Study Group (SSSG) was formed to answer questions about scleral shape in normal and diseased eyes, allowing scleral lenses to be fitted with a greater understanding of the shape of the tissue on which it lands.

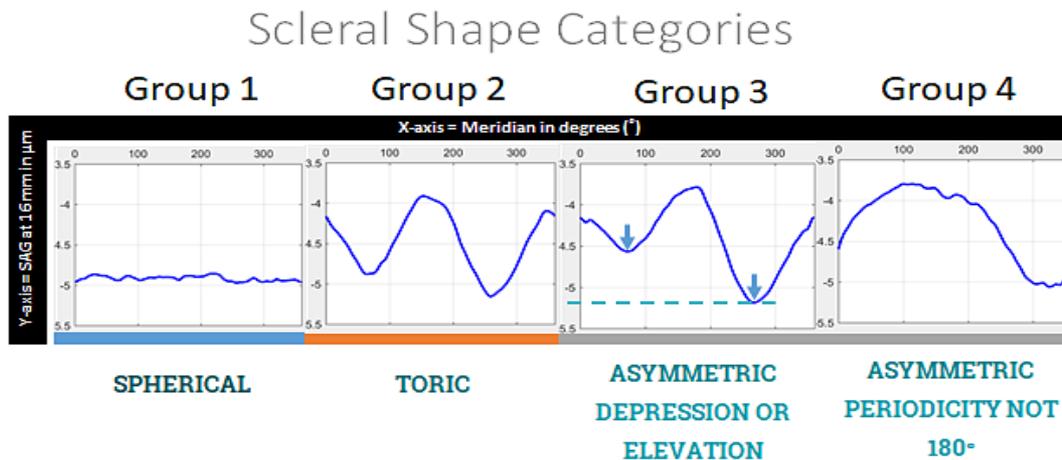
Once believed to be spherical, it has been shown that the sclera is shaped non-symmetrically aspheric and can show high intra and interpersonal variability.^{1,2} A new classification system of scleral shape patterns using circumferential scleral shape plots was recently described.³ Briefly, four shape groups were determined after analysis of the plots taken on a circumlinear curve at a 16-mm diameter (8-mm radius) chord centered on the geometric corneal center. The first group (Group 1) was defined as having a spherical shape characterized by ≤ 300 μm in sagittal height difference between the highest and lowest point of scleral elevation. A second group was classified with a shape plot conforming visually to a periodicity of 180° and considered to have a regular pattern of toricity (Group 2). Individuals

with >300 μm difference in sagittal height between the 2 lowest points or between the 2 highest points, indicating greater amounts of asymmetry, were classified as Group 3. Finally, cases that did not conform to a periodicity of approximately 180° were considered not standard and part of Group 4 (Figure 1).

This classification did not take in account the shape of the cornea. However, a number of studies have attempted to compare corneal to scleral topography in normal eyes.⁴⁻⁶ The major variable being compared was magnitude and/or direction of corneal astigmatism vs. scleral asymmetry or toricity. Kinoshita, Morrison, and Caroline⁴ found the sclera to be asymmetric, but did not find any relationship between scleral toricity and the axis of the corneal astigmatism. Siebert and Jedlicka⁵ found that scleral shape is generally more against the rule than the cornea. Consejo and Rozema⁶ found that in patients with $>1\text{D}$ of corneal astigmatism, the axis and curvature of scleral shape were highly correlated with the cornea; however, there were no correlations in patients with <0.75 D of corneal astigmatism.

Others⁷ evaluated Placido-based corneal topography data and scleral lens fitting data (lens SAG; landing zone toricity) in irregular corneas and high refractive errors. While there was some association between lens SAG and topographer-predicted eye SAG, high variability limited the predictive value of this technique. The authors concluded that while high corneal toricity ($\geq 2\text{D}$) can help predict whether

FIG. 1 An example of each scleral shape category. The X-axis in each graph is the axis of the data points on a polar scale. The Y-axis is the SAG data from a circumferential curve at a 16-mm diameter around the corneal center; the Y-axis is inverted with higher SAG values lower down on each graph. All 4 graphs above have the same Y-axis scaling.



the subject would need a toric landing zone, there was no relationship between corneal toricity and the need to fit a toric haptic design in cases with irregular corneas.

Another study⁸ looked at differences in corneo-scleral profile between patients with healthy (88 eyes of 88 patients) and keratoconic (21 eyes of 11 patients) corneas. They studied 45 separate variables and applied tests of statistical significance to these variables 175 times. The main corneal differences reported between the keratoconic eye and the normal eye were as follows: in keratoconic eyes, they found a significantly lower inferior limbal tangent angle, a higher temporal sagittal height at 11-, 12-, and 13-mm chords, larger differences between temporal and nasal sagittal heights at 12- and 13-mm chords and the maximum sagittal height at a 12-mm chord. These differences were not found when the data from the least severely affected keratoconic eye was compared to normal eyes. This study also attempted to correlate 9 scleral variables to 7 corneal ones in 56 separate comparisons, separately for the normal and keratoconic group. While a large number of significant correlations exist between cornea and sclera in the normal cornea group, the

authors were not able to confirm this finding in the keratoconus group.

To complete these previous works, this study aims to determine if there is a relationship between corneal and scleral topography shape asymmetries based upon corneal ectasia location. It aims also to determine if these observations could be found in patients with normal corneas. The clinical significance and practical applications of these findings will also be discussed.

METHODS

This is a retrospective study performed in compliance with the Declaration of Helsinki. Ethics committee approval was obtained from Advarra IRB, covering all sites¹ participating in this study. During transfer and subsequent analysis, patient anonymity was protected. All files submitted came from subjects who underwent assessment with a corneo-scleral elevation topography system (sMap 3D, Visionary Optics, US). Subjects from every site were assigned by their investigator to 2 groups based on their clinical presentation and corneal profile: patients identified as having normal corneas by the investigator and appearing to have a normal prolate shape with no observable

corneal abnormalities on corneal elevation topography (Group A) or corneal ectasia clearly visible on corneal elevation topography (Group B); these assignments were confirmed by one of the authors, after a second review of the maps transferred.

Non-reliable mapping of the ocular surface at a 16-mm diameter were excluded as well as those coming from post-surgery corneas. If the presence of a filtering bleb or pinguecula was detected or any other artefact that may confound the potential cornea-scleral relationships, it was also excluded.

Mapping the Sclera

The following examples will illustrate how it is possible to extract specific information about the shape of the cornea and the conjunctiva/sclera based on the maps generated by the ocular surface profiler.

Figure 2 illustrates how shape data of the cornea and the conjunctiva/sclera is extracted from the maps generated by the ocular surface profiler. The topographical image is a color-coded scleral elevation map of an individual eye. The center area of the cornea is a uniform color because the scale has been optimized for the conjunctival/scleral surface. SAG values are determined at a fixed 16 mm diameter from the corneal center in this example. The graph illustrates a depressed area, with a higher sagittal height (colder-blue color on the left map), alternating with a more

elevated area, generating a lower SAG (warmer- red color) approximately every 90°.

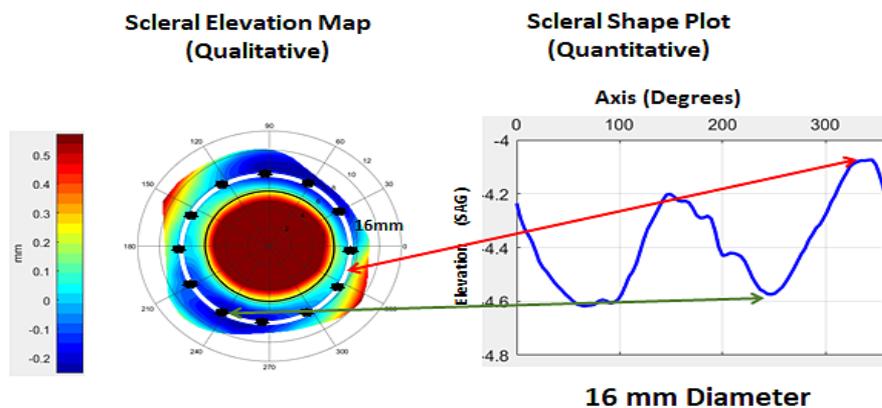
Each data point collected on the circumferential curve is plotted to generate an elevation plot (Figure 2, right). This particular case describes a regular-shaped toric (Sin^2) curve with a periodicity of 180°. In this right eye, the main or steep axis is supero-nasal and infero-temporal.

Mapping the Cornea

The cornea can also be evaluated using the same mapping technique, and these images allow the evaluation of corneal asymmetry as well as the relationship of corneal to scleral asymmetries. Figure 3 (left) demonstrates a color-coded corneal elevation map of a case with an inferior ectasia; the apex of the ectasia is at a radius of 2.3 mm (diameter 4.6 mm) from the center of the cornea at an axis of 270°, established by the meridian joining the apex of ectasia and the geometrical corneal center. The corresponding circumferential corneal shape plot (right), derived as previously described, provides quantitative data and shows the ectasia elevation. This plot shows that the SAG of the cornea is smallest at the apex of the ectasia

Another case is illustrated in Figure 4, demonstrating the differences between circumferential SAG measurements of the cornea (5 mm) and the

FIG. 2 Comparison of a qualitative scleral elevation map (left) which displays a color-coded map of scleral elevation using polar coordinates and a quantitative scleral shape plot (right). Arrows show similar points on the 2 maps.



sclera (16 mm) of a case with corneal ectasia. In this case, the highest point of corneal elevation is located at 280° and at a 5-mm diameter (2.5-mm radius, purple/yellow circle) from the geometric corneal center. Also shown is a red/yellow circle at an 8-mm radius (16-mm diameter) from the corneal center. Top black arrow shows the ectasia apex area

on the two corneal representations. Circumferential scleral shape plot derived from data from the 16-mm diameter circumference demonstrates that the lowest point (higher SAG) on the conjunctival/scleral surface is at 280° and the point 180° opposite (100° - red arrow) has a higher elevation and a smaller SAG (300 μm less).

FIG. 3 Case with inferior ectasia. The arrow demonstrates the axis of the apex of the ectasia in both images.

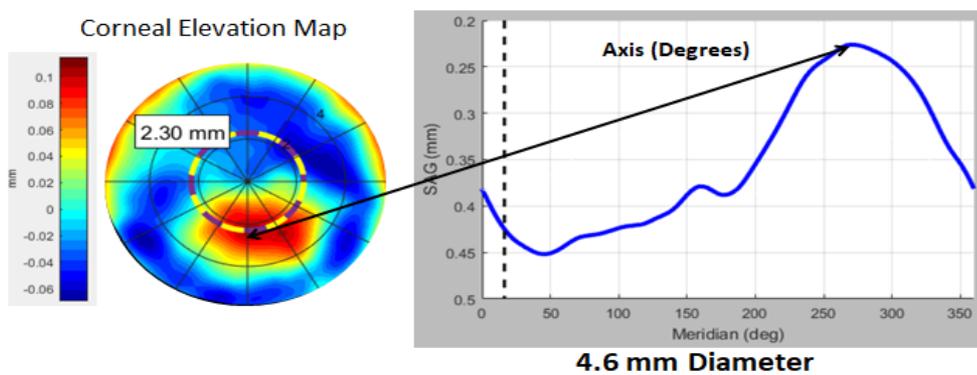
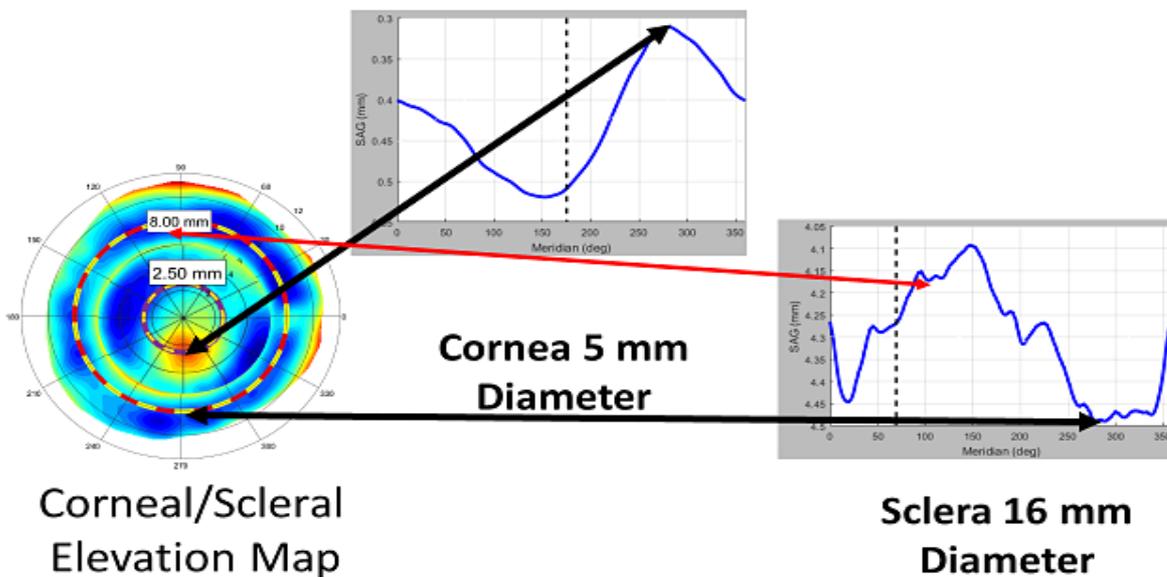


FIG. 4 Demonstrates both corneal and scleral elevation maps and corresponding corneal and scleral shape plots in a case with an inferior corneal ectasia.



This method of deriving corneal and scleral shape can be applied to ectasias at any corneal location, for example, a superior ectasia (Figure 5). Collectively, these cases represent ocular shapes in which the axis where the greatest corneal elevation lies (ectasia apex) corresponds to the axis of the lowest point on the sclera. In these cases, the low point on the scleral elevation map is often asymmetric to the SAG value 180° away at the same distance from the corneal center. This intra-meridional difference in SAG is defined here as the “quadrant-specific” effect.

Data Analysis

Group A population was composed with 115 eyes of 71 subjects with normal prolate corneas and Group B with 227 eyes of 166 ectasia subjects. Fifteen cases were removed based upon exclusion criteria.

Scleral elevation pattern was best observed on scleral shape plots as previously described above. All of the analysis parameters were extracted directly from the profiler software through a custom designed program. These included the axis of the corneal apex which was the highest elevation point within the central 9-mm diameter of the cornea (based on the corneal geometrical center), ocular surface SAG at a chord diameter of 16 mm along the axis of the corneal apex (SAG 1) and its opposite axis 180° away (SAG 2), (Figure 6).

Conjunctival toricity T and angular offset ϕ were determined by estimating the best-fit of the measured

sagittal height Z sampled at a circular cross-section for each θ_i to the equation:

$$(\theta, T, \phi) \equiv 2^T \sin^2(\theta + \phi)$$

via minimizing the root mean squared error (RMSE) given as:

$$RMS(T, \phi) = \frac{\sqrt{\sum_{i=1}^N (Z(\theta_i, T, \phi) - Z)^2}}{N}$$

The axis of the apex was converted in the right and left eyes to identify nasal and temporal areas for analysis.

Figure 7 demonstrates an example of 2 cases with similar amounts of calculated scleral toricity, the first one (left) showing a good correspondence between the 2 curves and the second one (right) a non-corresponding pattern. The first graph has a calculated scleral toricity of 354 μm and an RMSE value of 51 μm while the second graph demonstrates a calculated scleral toricity of 348 μm and an RMSE value of 417 μm .

Statistical Analysis

Observed values and difference estimates were generally summarized with mean and standard error. For interval level data comparisons between two groups, t-tests were performed; for comparisons of grouped or categorical data, Chi-square analyses were performed. A nominal p-value of $p < 0.05$ was

FIG. 5 A mapping of a superior ectasia, with corresponding shape plots.

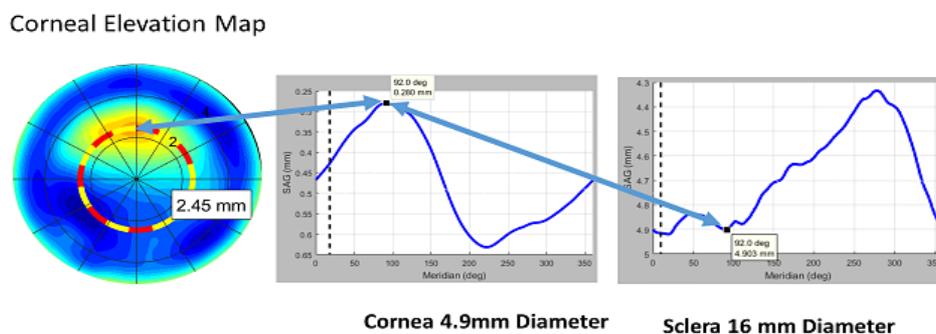


FIG. 6 Schematic demonstrating where the data is collected for this study; at the apex of an ectasia (black X), at a 16-mm diameter from the corneal center (yellow dotted circle) in the angle of the ectasia apex (red X), and in the angle 180° away from the ectasia apex (blue X).

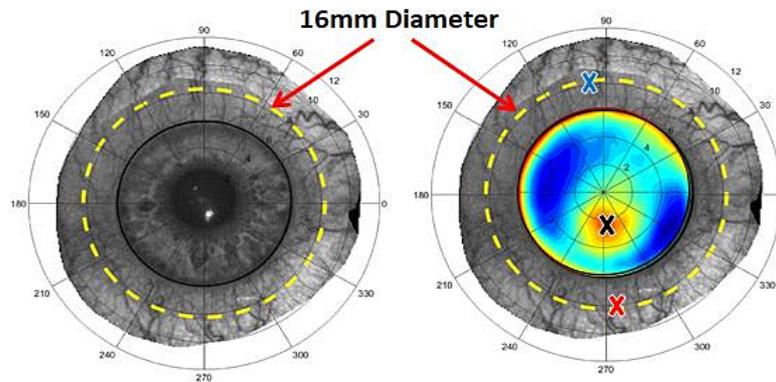
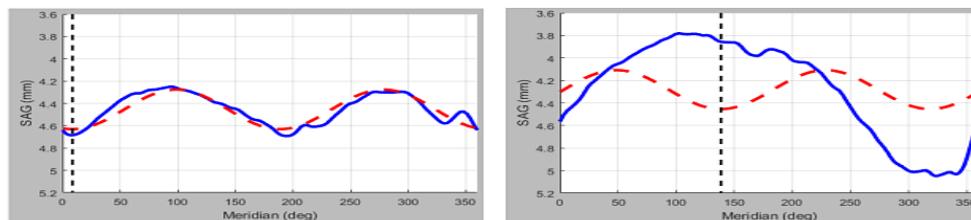


FIG. 7 Scleral shape plots at a 16mm diameter. Blue lines are the actual eye surface plots and the dotted red lines are best fit Sin^2 curves. The amount of standard toricity, is defined as the difference in SAG from the highest point to the lowest point on the best fit graph.



considered statistically significant. Where appropriate, analyses were corrected for dependence between eyes for subjects presenting bilateral information. Data were managed and analyzed using Excel (Microsoft, Redmond, WA) and SAS software, version 9.4 (SAS Institute, Cary, NC)

RESULTS

Table 1 summarizes the findings of this study. These results indicate significant differences between both groups, based on average quadrant specific effect (QSE) (A: $17 \pm 20 \mu\text{m}$ vs. B: $207 \pm 18 \mu\text{m}$; $p < 0.001$) and standard toricity (A: $172 \pm 9 \mu\text{m}$ vs.

B: $217 \pm 9 \mu\text{m}$; $p < 0.001$). In Group A, the QSE was not significantly greater than zero ($p > 0.05$) while it was significant in group B ($p < 0.001$). QSE versus standard toricity (ST) was found significant for group A (difference of $45 \mu\text{m}$) while the small variation in group B ($10 \pm 20 \mu\text{m}$) was not found statistically different. The RMSE value in group A was lower than in the group B ($96 \pm 5 \mu\text{m}$ vs. $133 \pm 5 \mu\text{m}$; $p < 0.001$).

It is interesting to note that QSE was not easily demonstrated if the apex was located $< 1.25 \text{ mm}$ from the corneal center, a subgroup of subjects (Group B2) constituting 37% of our irregular cornea population (Table 2). In fact, for these subjects, QSE and RMSE

TABLE 1. QSE, ST and RMSE Findings for Groups A and B

Parameter Studied @ 16mm Chord	Group A (Mean ± Standard Error in μm)	Group B (Mean ± Standard Error in μm)	p-Value-Group A vs B
QSE	17 ± 20	207 ± 18	p < 0.001
ST	172 ± 9	217 ± 9	p < 0.001
RMSE	96 ± 5	133 ± 5	p < 0.001

TABLE 2. The Effect of Corneal Apex Position on QSE, ST and RMSE.

Parameter Studied @ 16mm Chord	Group B2 (Mean ± Std Error in μm)	p-Value vs. Group A	Group B3 (Mean ± Std Error in μm)	p-Value vs. Group A	p-Value Group B2 vs. B3
QSE	66 ± 24	p > 0.05	289 ± 22	p < 0.001	p < 0.001
ST	210 ± 15	p = 0.028	220 ± 11	p > 0.001	p > 0.05
RMSE	101 ± 5	p > 0.05	151 ± 6 μ	p > 0.001	p < 0.001

value were both not significantly different from group A (p > 0.05). ST was statistically lower in group A vs. B2 (p = 0.028). In Group B2, the average standard toricity was 210 ± 15 μm and QSE was 66 ± 24 μm , which represents a significant difference between these 2 values (p < 0.001). The B2-RMSE value was 101 ± 5 μm , not significantly higher than group A (96 ± 5 μm , p > 0.05). The remaining 63% of our irregular cornea population were cases where the apex was located ≥ 1.25 mm from the corneal center (Subgroup B3). This reasonably obvious dividing point between groups B2 and B3 at approximately 1.25 mm was observed by visual observation of the QSE and RMSE variables as the distance from the apex increased. Table 2 provides a side-by-side findings allowing comparison of Group B2 versus B3. QSE and RMSE were significantly different (p < 0.001), reflecting more asymmetry in the latter group; ST was found similar in both groups (p > 0.05). QSE was strongly present if apex location was >1.25 mm from the corneal center. QSE reached 289 ± 22 μm , significantly different than group A (p < 0.001). A majority of B3-subjects (61%) had QSE > 200 μm , 45% showed a difference of >300 μm and 28% had

>400 μm difference. ST was evaluated as 220 ± 11 μm , again statistically different than group A (p = 0.001). This subgroup was the only ectactic group showing ST being significantly less than QSE (-69 ± 26 μ , p < 0.01). Finally, the B3-RMSE value was 151 ± 6 μm , significantly higher than group A (96 ± 5, p < 0.001).

A significantly greater proportion of ectasia cases were found in the groups with irregular sclera shapes (Groups 3 and 4, 129/227 [57%]) compared to prolate corneas (29/115 [25%], p < 0.001 -see Figure 8)

Patients graded as having regular conjunctival/scleral shape (Groups 1 and 2) had significantly lower RMSE values than those graded as having irregular shapes (Groups 3 and 4) in both the cases with corneal ectasias (85 ± 4 μm vs. 169 ± 6 μm , p > 0.001) and the cases with normal corneas (78 ± 27 μm vs. 150 ± 15 μm , p > 0.001).

The location of the axis of the apex is shown in Figure 9. Sixty-two percent of the axes were inferior (240–299°), 18% were infero-nasal, 9% were infero-temporal, 7% were supero-nasal, 2% were supero-temporal and 2% were superior (61–120°); thus 89% had ectasia apices inferior to the horizontal.

FIG. 8 Proportion of cases in the ectasia and no corneal irregularity data sets having scleral shapes graded as regular (Groups 1 and 2) or irregular (Groups 3 and 4).

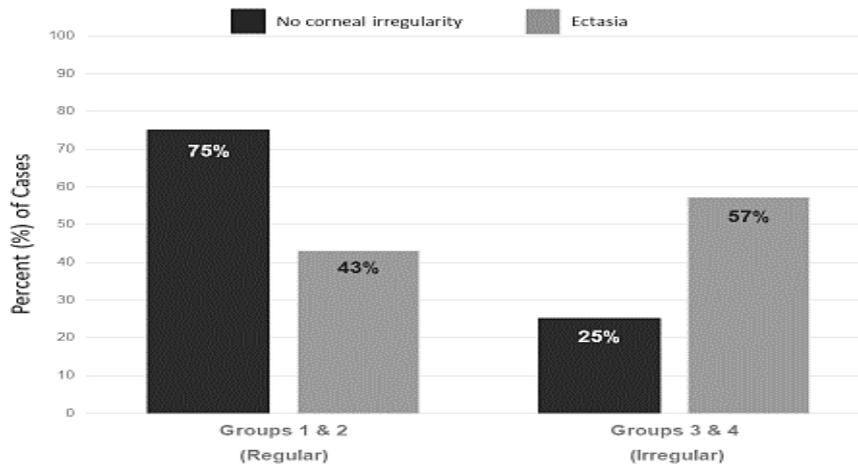
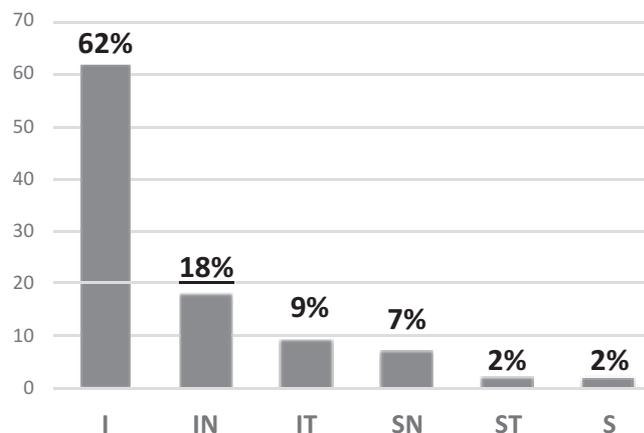


FIG. 9 Location of the axis of ectasia. Nasal and temporal areas had different axes in right and left eyes. *I = Inferior; IN = Inferonasal; IT = Inferotemporal; SN = Superonasal; ST = Superotemporal; S = Superior.*



DISCUSSION

The results of this study suggest that the conjunctival/scleral surface elevation varies along the same axis when ectasia affects the cornea, and if its apex is located over 1.25 mm from the geometrical center of the cornea. This difference of elevation along the same meridian 180° apart is defined here as a quadrant specific effect. This should be differentiated from regular ocular surface toricity, defined as the difference of ocular surface elevation between 2 principal axes, 90° apart.

This finding may significantly influence the way scleral lenses are currently designed for keratoconus subjects. Increasingly, it has been recognized that many patients presenting for scleral lens fitting do better with scleral lenses designed with toric peripheral curves rather than spherical ones.^{9–11} However the current study results suggest that neither of these may be the best alternative for those with corneal ectasias. In fact, these subjects would benefit from scleral lens designed with differing peripheral SAG values 180° apart or quadrant specific peripheral designs. Further clinical

studies, comparing peripheral profiles, are needed to confirm this hypothesis on a large population.

For the moment, it is possible to rely on others' work to validate this hypothesis. On a limited basis, a recent study,¹² using lenses designed from scleral shape plots analysis, demonstrated the value of fitting quadrant specific designed scleral lenses when other options failed.

To date, quadrant specific designs have been recommended in two situations. The first one is when obvious compression in a single quadrant was observed under slit lamp or was detected using Optical Coherence Tomography (OCT). The same recommendation applies when the edge of the lens, lifting off the ocular surface, is observed or objectively measured. There has been little indication up until now that a large number of patients may benefit from quadrant specific lenses. This may change considering that this study shows that quadrant specific SAG differences are significantly larger than standard toricity in ectasia patients when the corneal apex is not within the central 2.5-mm diameter of the cornea. Consequently, for these patients, quadrant specific lenses may be needed to improve the fitting and the outcome.

The RMSE value quantitates how well a given conjunctival/scleral shape will fit a standard spherical or toric peripheral curve system. The fact that this value was significantly higher in ectasia cases (Group B) than those with prolate corneas (Group A) suggests a possible association between corneal and conjunctival/scleral shape when ectasia progresses. The increased RMSE value in patients with non-central vs. central ectasia further suggests that asymmetric corneas are associated with asymmetric scleras. This relationship between corneal and conjunctival/scleral shape is further reinforced by the finding that the irregular scleral shape category groups (Groups 3 and 4) were found in 57% of cases with ectasia but only 25% of cases with normal prolate corneas. The previously reported scleral shape categories were validated, in turn, by the finding that patients graded as having regular shapes (Groups 1 and 2) had significantly lower RMSE values than those graded as having irregular scleral shapes (Groups 3 and 4) regardless of whether the ectasia series or normal cornea series was evaluated.

One major difference between a previous study including keratoconus cases⁸ is that the location and the orientation of the corneal ectasia was considered in the current study. As a result, it was found to be highly statistically significant in evaluating its relationship to scleral shape changes. This difference could explain why the previous study did not reach statistical significance between corneal and scleral findings. The current study also had a higher statistical power, relying on a much larger sample size in the ectasia group with much fewer parameters to compare.

This study was not designed to show whether it is the cornea or the conjunctival/scleral shape that drives or helps determine the other's shape. This has been previously discussed in prior publications.^{6,8} It is interesting to speculate that the shape of the sclera is influencing the position of the corneal apex for patients with corneal ectasia. Perhaps, the influence of the conjunctival/scleral shape is what causes many patients with ectasia to have inferior apices or the rare case of superior ectasia. Further studies will be needed to explore these elements more specifically.

It has been reported that there are other potential influences on conjunctival/scleral shape, including from the insertion differential between the extra-ocular muscles.¹² Differences in this factor could result in individual eyes with ectasia that don't follow the patterns that are presented in this paper.

There are a number of limitations to this study. Being a retrospective study, the inclusion criteria were determined by the individual sites although the presence of ectasia or normal prolate pattern was confirmed by a second review made on corneal topography. The study was theoretical in that it was confined to measuring scleral shape and did not clinically test various lens designs for their ability to fit well in individual eyes. In the absence of age, gender, ethnicity and other demographic information it is difficult to extrapolate these results to other clinical populations. It is also important to specify that the results reported here were evaluated at 16 mm chord diameter geometrically centered on the cornea, and consequently can be applied only to the fitting of scleral lenses of a similar diameter or larger, regardless of their primary functional diameter (where the

lens lands). The 16 mm chord diameter was chosen for consistency since it was the diameter used in the previous study defining scleral shape patterns.³ Other conclusions may be derived from analysis at other diameters. More especially, the use of smaller diameter scleral lenses, with a shorter landing area, may be less impacted by conjunctival shape and toricity, knowing that these elements increase further away from the limbus.¹

CONCLUSION

This study demonstrates that corneal irregularity is highly associated with higher conjunctival/scleral irregularity. The location of ectasia seems to play a significant role. The fitting of scleral lenses in such irregular ocular surfaces may necessitate a quadrant-specific approach to best optimize the lens to eye relationship, and to potentially improve the outcome.

COMPETING INTERESTS

G. DeNaeyer, D. R. Sanders, and T.S. Farajian are shareholders in Precision Ocular Metrology, the manufacturer of the sMap3D instrument and T.S. Farajian is an employee. D. R. Sanders is a shareholder of Visionary Optics, and G. DeNaeyer is a consultant to Visionary Optics. Visionary Optics distributes the sMap3D. No other authors have a competing interest

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